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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,092	09/22/2005	Ana Velasco Iglesias	13566.105008	7526

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1652	

NOTIFICATION DATE	DELIVERY MODE
11/28/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/540,092	VELASCO IGLESIAS ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-45* is/are pending in the application.

4a) Of the above claim(s) *1,16,17,28-31 and 33-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-15,18-27,32 and 43-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action mailed March 13, 2007 on September 13, 2007 is acknowledged. Applicant's request for clarification on claim 34 was addressed in the March 13, 2007 office action with the indication that the claim was withdrawn as directed to a non-elected invention (see page 2, item 2 of the office action). Claim 34 properly belongs in Group V with claim 33. Applicant is reminded that the proper identifier for claims withdrawn bearing amendment is "Withdrawn and Amended" (see for example claim 33) and the status of claim 34 should be changed from "Original" to "Withdrawn".

Restriction Requirement

2. On page 13 of the response applicant provides again a traversal argument, indicating that Groups II and III share a special technical feature. This argument is not persuasive as unity of invention is broken as evidenced by the cited prior art. Further, the encoding of a protein by a DNA is a technical feature, not a special technical feature as such can be achieved by any DNA. Thus, the Restriction Requirement is proper and final.

Applicant's on page 14 of the response state that a new Restriction Requirement was set forth and that the original Restriction Requirement should have been withdrawn and that finality of an office action preceding this would be improper. The first office

action clarified the initial Requirement made, however, no change was made to the elected group. Furthermore, claim 34 was inadvertently left off the Requirement, however, does not belong in the elected group. The clarification made of the Restriction Requirement in no way affected the examination of the elected claims, therefore does not impact the finality of the office action.

Claim Disposition

3. Claims 43-45 have been added. Claims 1-2 and 4-45 are pending. Claims 2-15, 18-27, 32 and 43-45 are under examination. For clarification purposes claims 1, 16-17, 28-31 and 33-42 are withdrawn as directed to a non-elected invention.

Maintained-Specification Objection

4. The specification is objected to because of the following informalities:

The specification is objected to because the abstract has an improper sentence structure, see the disclosure of "A gene cluster has open reading frames, which encodes polypeptides...", it is suggested that the language is amended to read for example, "A gene cluster having an open reading frame which encodes polypeptides...". It is also suggested that SEQ ID NO:1 is recited in the abstract for completeness.

Maintained-Sequence Compliance

5. It is noted that applicant filed a new sequence listing on September 13, 2007 and a sequence statement. The sequence statement indicates that no new matter is included, however does not state that the computer readable form and sequence listing is identical. According to the sequence rules, "to be in compliance, applicant is required to identify all amino acid sequences of at least 4 L-amino acids and at least 10 nucleotides by a sequence identifier, i.e., "SEQ ID NO:".... provide a computer readable form of the "Sequence Listing" including these sequences, a paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable form copies are the same and, where applicable, include no new matter as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), (emphasis added).

Information Disclosure Statement

6. The Information Disclosure Statement filed on September 13, 2007 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Withdrawn-Claim Objection

7. Previous objections to the claims are withdrawn by virtue of submission of an amendment.

Withdrawn- Claim Rejections - 35 USC ∋ 101

8. Previous rejections to the claims under 35 U.S.C. 101 is withdrawn by virtue of submission of an amendment.

New-Claim Objections

9. Claims 2 and 18 are objected to because of the following informalities:

For clarity it is suggested that claim 2 is amended to recite "is a full complement" in lieu of "fully complementary" because this language does not necessarily reflect a complement over the entire sequence. The claim is missing the article "and" between "a-b", thus improper claim language.

For clarity and precision of claim language it is suggested that claim 18 is amended to recite "the nucleic acid sequence of claim 1", in lieu of "a nucleic acid sequence", since the claim is referring to a specific one and the article "a" is indefinite.

New-Claim Rejections - 35 USC ∋ 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

10. Claims 14-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. Note that claim 14 is directed to a method of

detecting however, the method has no positive method steps. The method reports that method comprises hybridizing a probe according to claim 11 and claim 11 is directed to a product, "a hybridization probe". Thus, claim 11 does not provide a method of hybridization to rectify the deficiency in claim 14 and claim 14 only requires the use of the specific probe claimed in claim 11. Note also that claim 15 recites the method of claim 14 and simply provides a host cell. Thus claims 14-15 do not set forth what method/process is encompassed. Without setting forth any steps involved in the process/method, results in an improper definition of a process and are not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

11. Claims 21-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 21 and the dependent claims are drawn to a host cell, which reads on a product of nature. The claim, as written, does not sufficiently distinguish over cells as they exist naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. In the absence of the hand of man, the naturally occurring product is considered non-statutory subject matter. See *Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980)*. The claims should be amended to indicate the hand of the inventor, for example, by the insertion of "isolated" (or as in

claim 26 "recombinant") in connection with the host cell to identify a product not found in nature (see MPEP 2105).

Maintained and Amended-Claim Rejections - 35 USC э 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 2-15, 18-27, 32, 34 and 43-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabled for the full scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the

art and Breadth of the claims (see *In re Wands, 858 F.2d at 737, 8 USPQ2d at1404 (Fed. Cir. 1988)*. The factors most relevant to the instant invention are discussed below.

The claimed invention is directed to a nucleic acid and variants or portions thereof as well as variants or portions thereof of the encoded peptide synthetase, and any safracin analogue. In addition, the claims recite the open language "comprising", thus the claims encompass a large variable genus of variants/derivatives. Further, claims such as claim 5 recite " 30% sequence identity for the encoded peptide, however, no reference structure is provided in association with the recited percentage. Additionally, the claims are directed to a probe subjected to stringent hybridization conditions, however, no conditions are provided in the instant claims. The claims are also directed to a method of detection which is inoperable based on the absence of method steps. Due to the large quantity of experimentation necessary to generate the infinite number of variants/derivatives recited in the claims and possibly screen same for activity and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation. Thus, undue experimentation would be required for a skilled artisan to make and/or use the claimed invention commensurate in scope with the claims.

Moreover, neither the claims or the instant specification identifies conserved regions/domains for the variants or where in the sequences modifications can occur or what modifications can be tolerated by the claimed structures. Note that claims such as claim 8 recites "wherein the portion is at least 50 nucleotides" and there is no

requirement for the nucleotides to be contiguous and the disclosed SEQ ID NO:1 has 26705 nucleotides. Therefore, no correlation has been made been structure and function. Thus, absent adequate guidance/direction one of skill in the art would not be able to practice the claimed invention commensurate in scope with the claims based on the disclosure in the art which renders the claimed invention as unpredictable. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

With regard to the recited 30% identity to the encoded protein, predictability of which potential changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (for example, expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, for example, multiple substitutions. In this case, the necessary guidance has not been provided in the specification. Therefore, while it is known in the art that many amino acid substitutions are possible in any given protein, the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited, as certain positions in the sequence are critical to the protein's structure/function relationship. It is also known in the art that a single nucleotide or amino acid change or mutation can destroy

the function of the biomolecule in many cases. For example, various sites or regions directly involved in binding activity and in providing the correct three-dimensional spatial orientation of binding and active sites can be affected (see Wells, Biochemistry, vol. 29, pages 8509-8517, 1990). The instant specification provides no guidance/direction as to which regions of the protein would be tolerant of modifications and which would not, and it provides no working examples of any variant sequence that is encompassed by the claims. It is in no way predictable that randomly selected mutations, such as deletions, substitutions, additions, etc., in the disclosed sequences would result in a protein having activity comparable to the one disclosed. As plural substitutions for example are introduced, their interactions with each other and their effects on the structure and function of the protein is unpredictable. The skilled artisan would recognize the high degree of unpredictability that all the variants encompassed in the claims would retain the recited function.

The state of the prior art provides evidence for the high degree of unpredictability as stated above. Seffernick et al. (J. Bacteriology, vol. 183, pages 2405-2410, 2001) disclose two polypeptides having 98% sequence identity and 99% sequence identity, differing at only 9 out of 475 amino acids (page 2407, right column, middle and page 2408, Fig. 3). The polypeptides of Seffernick et al. are identical along relatively long stretches of their respective sequences (page 2408, Fig. 3), however, these polypeptides exhibit distinct functions. The modifications exemplified in the Seffernick et al. reference is small compared to those contemplated and encompassed by the claimed invention.

The specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims. Furthermore, while recombinant and mutagenesis techniques are known in the art, it is not routine in the art to screen large numbers of mutated proteins where the expectation of obtaining similar activity is unpredictable based on the instant disclosure. The amino acid sequence of a protein determines its structural and functional properties, and predictability of what mutations can be tolerated in a protein's sequence and result in certain activity, which is very complex, and well outside the realm of routine experimentation, because accurate predictions of a protein's function from mere sequence data are limited, therefore, the general knowledge and skill in the art is not sufficient, thus the specification needs to provide an enabling disclosure.

The working examples provided do not rectify the missing information in the instant specification pertaining to the claimed variant. The nature and properties of this claim is difficult to ascertain from the examples provided as one of skill in the art would have to engage in undue experimentation to construct the variants/derivatives of the claimed invention and examine the same for function.

The specification does not provide support for the broad scope of the claims, which encompass an unspecified amount of variants/derivatives of the protein. The claims broadly read on any derivatives thereof. The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the

decisions of *In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).*

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to construct and test derivatives of the claimed invention would constitute undue experimentation. Making and testing the infinite number of possible variants to find one that functions as described is undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

13. Claims 2-15, 18-27, 32, 34 and 43-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a nucleic acid or variant or portion thereof and a variant or portion thereof of the peptide encoded thereby, and any safracin analogue. In addition, the claims recite "at least 30% identity to the peptide" thus the claims encompass a large variable genus of variants and derivatives. Moreover, the claims are directed to a method having no positive method steps, hence inoperable and to hybridization absent specific hybridization conditions. The claims are directed to a genus of nucleic acids and proteins that are not adequately described as a skilled artisan cannot envision the detailed chemical structure of the derivatives encompassed in the claims. The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials'. University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described, are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Further, no relationship between the disclosed species and the structures of the other proposed species is described. Thus, one of skill in the art would be unable to predict the structure of other members of this genus based on the instant disclosure. Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Further, *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991)*, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. *See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993).*

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

14. Claims 4-5, 11-15 and 43-45 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claims 4-5 lack clear antecedent basis for the recitation of "at least one of the sacA... genes" because claim 2 from which it depends makes no mention of any genes.

Claims 11-15 are indefinite for the recitation of "stringent conditions" absent specific hybridization conditions because it is unclear what values to equate with that terminology since the art recognizes that hybridization conditions can vary, especially the wash conditions. Thus, the metes and bounds is unclear.

Claim 5 remains indefinite because the claim recites "at least 30% identity" and the claim does not provide a reference sequence for the peptide. See also claim 45 with the same language.

Claims 43-44 lack clear antecedent basis for the recitation of "at least one of the sacABCDE..." because claim 2 from which it depends makes no mention of any of these genes.

New-Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 2, 4-10, 18-22, 24-27, 32 and 43-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Pospiech et al. (Microbiology, vol. 141, pages 1793-1803, February 18, 1999) based on the broad recitation of variant or portion thereof.

Pospiech et al. teach a gene cluster derived from *Myxococcus Xanthus* DM504/15. The reference teaches that tagged genes were cloned and used to select overlapping cosmids. These genes were sequenced and a region encodes two amino acid domains with similarity to peptide synthetase (a non-ribosomal multienzyme

complex). The reference sequence is a portion or variant thereof for the claimed SEQ ID NO:1 and thus is homologous to SEQ ID NO:2. The reference teaches the use of plasmids and the transformation of *E. coli* with the expression vector. The reference also teaches gene disruption experiments (see pages 1793 and 1796 of the reference). Therefore, the limitations of the claims are met by the reference.

Response to Applicant's Arguments:

16. The response has been considered in full, however is not persuasive. Note that the objection to the abstract remains. It is noted that applicant states that amendments were made, however, no amendments were found. In addition the application remains noncompliant with the sequence rules as stated above because the sequence statement is not complete. Note that new rejections have been instituted or remaining rejections have been amended to include an examination of claims 11-15 and 18-27 which were previously not treated on the merits based on a multiple dependent claim problem. However, the examination of these claims does not preclude the finality of the office action because the modifications in the application are a direct result of amendments made to the claims. Note however, that the office action is non-final because a new rejection was introduced under 35 U.S.C. 112, second paragraph. Applicant's comments regarding a corrected filing receipt is noted and response will be mailed under a separate cover.

Note that the previous rejection under 35 U.S.C. 101 has been withdrawn, however, new rejections have been instituted under this statue for the reasons stated above, based on amendments made to the claims.

The rejections under 35 U.S.C. 112, first and second paragraphs remain and have been amended. With respect to the 112, first paragraphs, applicant on page 17+ traverses the rejections with respect to the previously examined claims 2-10.. The rejections have been amended to include claims 11-15 and 18-27 which have similar issues as outlined above.

Applicant state that on page 12, lines 17-27 provides detailed information with respect to conserved regions in addressing the enablement rejection. At page 12 of the specification it is disclosed that "Fig. 2: Conserved core motifs between NRPSs. Conserved amino acid sequences in SacA, SacB and SacC proteins and their comparison with its homologous sequences from Myxococcus Xanthus DM50415". Claim 2 for example recites "An isolated nucleic acid sequence comprising: a) a nucleic acid sequence SEQ ID NO:1, or variants or portions thereof encoding at least one non-ribosomal peptide synthetase which catalyses at least one step of the biosynthesis of safracins"....Thus the claim broadly reads on any structure fragments or variants within SEQ ID NO:1 and does not require a contiguous run of sequences. The enablement rejections indicates that the claims are not commensurate in scope with the instant specification, in other words no support is found in the instant specification for the breath of the claims which encompass any nucleic acid variant or fragment that can be made from SEQ ID NO:1 which made not encode the recited protein. Thus applicant's arguments with respect to the disclosure in the specification is noted, however, in no way limits the claims. Furthermore, applicant is reminded that the limitations of the specification cannot be read into the claims. The instant remains remain overly broad and encompass a genus of variants for the nucleic acid and the encoded protein.

Applicant also state that active sites are identified (page 18 of the response), however no correlation is made between structure and function with the unlimited

amount of variants and fragments encompassed in the claims. The present claim language is not limited to a specific exemplification in the specification. Undue burden would be required to generate all the possible ones and screen for the activity.

Applicant's statements on pages 18-19 are noted, however, the issue at hand is the breath of the claims in light of the art and the disclosure in the specification. The claims broadly read on any nucleic acid structure with the recitation of "variants thereof or portions thereof" in association with the open language "comprising" . A broad variable genus is encompassed in the claims which is not supported by the instant specification. Applicant pointed to page 14, line 8 for example ("Within the deduced amino acid sequences of SacA, SacB and SacC, one peptide synthetase module was identified on each of the ORFs"), which does not breathe life into the claims since the claim is not limited to a specific structure having a specified function. Thus, the rejection remains because applicant's arguments are not persuasive.

The written description rejection is discussed on pages 19+ of the remarks. Applicant state that "the specification fully describes SEQ ID NO:1 as a species within the genus as claimed. This argument is not persuasive because the issue at hand is the large variable genus encompassed in the claim which is not adequately described by SEQ ID NO:1 alone. The claims read on a dipeptide from the structure of the encoded protein, thus applicants have not demonstrated possession of the entire genus claimed. Therefore, the rejection remains.

With respect to the rejections under 35 U.S.C. 112, second paragraph, applicant states that claim 2 is amended as suggested by the examiner. Note that a new objection has been made over the claim regarding the amendatory language. The previous office action on page 16 suggested "full complement' and the instant claim recites "fully complementary", as stated above the two terms are not equivalent. On

page 21 of the response applicant state that claim 5 does not need to be amended with respect to a reference sequence since the structure of the protein can be determined from the DNA. This argument is not persuasive because it is not clear what a structure that is 30% identical with look like since the claims encompass so much variability with respect to not requiring a contiguous sequence, reading on a dipeptide for the encoded sequence and "comprising any variant or portion thereof". Thus, SEQ ID NO:1 might not be the structure following the extensive modifications, a reference structure is needed.

The rejection under 35 U.S.C. 102(e) has been withdrawn and replaced with a 102(b) in view of amendments made to the claims and arguments presented.

Conclusion

17. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Primary Examiner 1/23/07

HOPE ROBINSON
PRIMARY EXAMINER